

 hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

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### **REMARKS**

#### **The Present Invention**

The present invention is directed to a formulation consisting essentially of a fibrate dissolved in at least one oil and an emulsifier that is capable of forming an emulsion upon dilution in an aqueous medium.

#### **The Office Action**

The Office Action made the following rejection:

1) claims 1, 3 and 7-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. (U.S. Patent No. 5,645,856).

#### **Discussion of 35 U.S.C. §103(a) Rejection**

The Examiner has rejected claims 1, 3 and 7-12 under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. The Examiner stated that "Lacy et al. (U.S. Patent No. 5,645,856)

teaches a carrier system for a hydrophobic drug (including finofibrate [fenofibrate]) composition comprising (a) a digestible oil (including soybean oil, coconut oil, corn oil, palm oil, cottonseed oil, olive oil, safflower seed oil); (b) a pharmaceutically acceptable surfactant comprising a hydrophilic (including phospholipids, poly[oxy]ethylene sorbitan fatty acid derivatives, castor oil or hydrogenated [ester] castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropyl[k]ene co-polymers[,] and block co-polymers) and a lipophilic surfactant (including propylene glycol), see in particular col. 3, lines 38-67, cols. 5-9[,] and col. 11[12], lines 22-23, see col. 21[,] example 6, lines 21-31."

The present invention claims compositions consisting essentially of a fibrate dissolved in at least one oil with one emulsifier. Claim 1 as presently amended restricts the selected <sup>one oil + one emulsifier</sup> emulsifier to either a lipophilic or a hydrophilic surfactant (not both), and would avoid the use of a surfactant (emulsifier), as disclosed by Lacy et al, comprising a hypophilic surfactant component. Thus the claims are not obvious in view of Lacy et al. and this rejection should be withdrawn.

### Conclusion

Applicants respectfully request favorable consideration and allowance of claims 1, 3 and

7-12 as presently amended. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 23-0785.

Respectfully submitted,

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**Marked-Up Version of Claims**

1. (thrice amended) A composition consisting essentially of a fibrate dissolved in at least one oil with one [or more emulsifiers] emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate [and combinations thereof] wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.